IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICANT	: Jackowski *et al.*
INVENTION	:**Plasma Protease C1 Inhibitor Biopolymer Markers Indicative Of Alzheimers Disease**
SERIAL NUMBER	: 09/991,799
FILING DATE	: November 23, 2001
EXAMINER	: Chernyshev, Olga N.
GROUP ART UNIT	: 1646
OUR FILE NO.	: 2132.086

#13
B.G.J
9/25/03

CERTIFICATE UNDER 37 CFR 1.8(a)
I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 on 8-19-2003

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DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to represent the inventor's and assignee in the application entitled **"Plasma Protease C1 Inhibitor Biopolymer Markers Indicative Of Alzheimers Disease "**, having U.S. Application Serial No. 09/991,799 filed November 23, 2001.

2. In the Office Action mailed on May 19, 2003, claims 1 and 2 were rejected under 35 U.S.C. 112, first paragraph because the claimed invention allegedly contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims as amended have been limited to a specific biopolymer marker peptide consisting of amino acid residues 2-18 of SEQ ID NO:1 (the 1826 dalton marker)useful in methods and kits for diagnosing Alzheimers disease. The method of the invention as recited in claim 39 involves a comparison of the mass spectrum profile of a peptide consisting of amino acid residues 2-18 of SEQ ID NO:1 to mass spectrum profiles of peptides elucidated from a patient sample, wherein recognition of a mass spectrum profile in the patient sample displaying the characteristic profile of the mass spectrum of the peptide consisting of amino acid residues 2-18 of SEQ ID NO:1 indicates that the patient from which the sample was obtained is suffering from Alzheimers disease.

3. In order to provide data which would further support the ability of the claimed peptide to function as a diagnostic for Alzheimers disease, I contacted Dr. George Jackowski, Chairman and Chief Science Officer of Syn-x Pharma Inc., and asked to be provided with evidence of the absence of the 1826 dalton marker in normal human sera (obtained from healthy patients).

4. This declaration (including the attached figure) is provided in order to show a comparison of the serum profile of individuals having Alzheimers disease to the serum profile of non-diseased individuals, so as to evidence that the marker (the 1826 dalton peptide) was not present in normal human sera.

The attached figure, obtained from Dr. Jackowski from data derived from the original experiments carried out at the time of conception of the instant invention, provides side-by-side profiles (obtained using techniques of mass spectrometry) of normal human sera versus sera from patients having Alzheimers disease. This profile comparison clearly evidences the absence of the 1826 dalton marker in normal human sera.

The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

8/18/2003
Date

Ferris H. Lander
Reg. No. 43,377

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